K103476

JUN 16 2011

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date: November 23, 2010
Submitter: GE Healthcare, (GE Medical Systems, LLC)
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Waukesha, WI 53188
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GE Healthcare, (GE Medical Systems, LLC)
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Device Identification:

Trade Name: Brivo XR285amx ; Optima XR200amx ; Optima XR220amx
Common/Usual Name: Brivo XR285amx – Analog Mobile
Optima XR200amx – Digital Ready Mobile
Optima XR220amx – Digital Mobile
Classification Names: Brivo XR285amx ; Optima XR200amx ; Optima XR220amx

Product Code: Class II, IZL, System, X-ray, Mobile, 21 CFR 892.1720
Predicate Device(s): AMX-4 Plus Mobile X-ray system K021016
GE Definium AMX700, Model AMX 700 K052897
WIRELESS DR IMAGING OPTION WDR1 K102615 (pending)

Device Description:

The GE Automatic Mobile X-Ray (AMX) Series: Brivo XR285amx, Optima XR200amx, Optima XR220amx are intended to take exposures utilizing film or computed radiography (CR), however the Optima XR220amx utilizes the GE Wireless Detector, which is intended to replace radiographic film screen systems in all general purpose diagnostic procedures, for digital radiography (DR).

Brivo XR285amx, Optima XR200amx, Optima XR220amx are self-contained; battery operated mobile radiographic imaging systems designed to generate diagnostic radiographic images (medical x-rays) that may increase the ability to detect disease or injury early enough for a medical problem to be managed, treated, or cured. Medical x-rays are used in many types of examinations and procedures, some examples include: x-ray radiography (to find orthopedic damage, tumors, pneumonias, foreign objects).

The series are indicated for use on adult and pediatric patients for general-purpose diagnostic radiographic examinations and procedures. Its mobility enables general-purpose radiographic procedures throughout the clinical environment, or as needed within the emergency, intensive care, premature birth ward, cardiac and operating departments, for patients that may not be able to be moved or in cases where it is unsafe or impractical to move them to a traditional RAD room.

The flat panel detector provides increased functionality to enable images of patients of all sizes, and can produce comparable quality images with as little as half the dose of traditional computer radiography (CR), cassettes and other flat panel detectors with lower DQE. The digital detector is designed to withstand a distributed load of 352Lbs to accommodate certain larger patients.

The systems are indicated for taking radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts with the patient sitting, standing, or lying in the prone or supine position.

These devices are not intended for mammographic applications.

Indications for Use:

The GE Automatic Mobile X-Ray (AMX) Series: Brivo XR285amx, Optima XR200amx, Optima XR220amx are intended to take exposures utilizing film or computed radiography (CR), however the Optima XR220amx utilizes the GE Wireless Detector, which is intended to replace radiographic film screen systems in all general purpose diagnostic procedures, for digital radiography (DR).

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Technology:

The Brivo XR285amx, Optima XR200amx, Optima XR220amx employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The Brivo XR285amx, Optima XR200amx, Optima XR220amx and its applications comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

Summary of Clinical Tests:

The subject of this premarket submission, [Brivo XR285amx, Optima XR200amx, Optima XR220amx], did not require clinical studies to support substantial equivalence.

Comparison with Predicate Devices:

The Brivo and Optima Systems are updated versions of the AMX4+ and Definium AMX700 products. The primary changes from the predicates are due to improved technology since the AMX4+ and AMX700 products were designed. Changes involve reduced overall size and weight of the product, improved charging efficiency, implementation of a dual focal spot tube, and higher power generator. Additionally in comparison to the AMX4+ product, the Brivo system has an integrated touch screen display for customer input. Modifications to implement these updates involve hardware, software and firmware changes. The Brivo and Optima systems are all for use in mobile x-ray radiology and have similar indications for use. Changes made to achieve the new system designs were made in hardware, software and firmware, but there is no fundamental change in the use of the product for mobile x-ray, nor in technology. It has the same technological characteristics related to safety and effectiveness as the predicate devices. A review of all bench and standards testing indicate that the new device provides no new safety concerns and is as safe an effective as the predicate devices. The Brivo and Optima systems are certified to comply with the X-ray requirements of 21 CFR, as well as safety requirements of IEC 60601-1 and associated collateral and particular standards.

Adverse Effects on Health:

The device has been evaluated for electrical, mechanical, and radiation safety, and conforms to applicable medical device safety standards, as confirmed by a Nationally Recognized Test Laboratory.

The potential hazards of electrical and mechanical are identified in a risk management summary (hazard analysis) and controlled by:

- System verification and validation to ensure performance to specifications, Federal Regulations, and user requirements.
- Adherence and certification to industry and international standards.
- Compliance to applicable CDRH 21 CFR subchapter J requirements.

The device is designed and manufactured under the Quality System Regulations of 21CFR 820.

Conclusion:

GE Healthcare considers the Brivo XR285amx, Optima XR200amx, Optima XR220amx to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

The Brivo and Optima systems are an improvement in design technology, and customer needs. It does not result in any new potential safety risks, has the same technological characteristics, and performs as well or better then devices currently on the market. The Brivo and Optima Systems will be certified to comply with the X-ray requirements of 21 CFR, as well as safety requirements of IEC 60601-1 and associated collateral and particular standards.

After analyzing standards testing and bench data, it is the conclusion of GE Healthcare that the Brivo and Optima Systems are substantially equivalent to other marketed devices with similar indications for use and meeting the same standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

JUN 16 2011

Ms. Nidhi Chaudhary
Regulatory Affairs Leader, X-Ray
GE Medical Systems, LLC
3200 N. Grandview Blvd.
WAUKESHA WI 51388

Re: K103476
Trade/Device Name: Brivo XR285amx, Optima XR200amx, Optima XR220amx
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL
Dated: May 1, 2011
Received: May 13, 2011

Dear Ms. Chaudhary:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known):

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_ (Part 21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K103476